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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/536,861	03/27/2000	Tibor Juhasz	11236.11MKH	3826
26271	7590	09/07/2005	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			SHAY, DAVID M	
1301 MCKINNEY			ART UNIT	
SUITE 5100			PAPER NUMBER	
HOUSTON, TX 77010-3095			3739	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/536,861	Applicant(s) JUHASZ	
	Examiner david shay	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 11, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment filed July 11, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "As discussed in U.S. Patent No. 4,988,348 to Bille et al., the pulsed laser beam 12 preferably has a fluence of more than 10 joules per square centimeter or more for the ablation of corneal tissue."

Applicant argues that U.S. Patent No 4,988,348, which is referenced in U.S. Patent No. 6,110,166, to which the instant application claims priority, supports the limitation of an "optimized pulse energy density above a minimum level". The examiner cannot agree. The only reference to U.S. Patent No 4,988,348 in U.S. Patent No 6,110,166 is in the context of U.S. Patent No 4,988,348 teaching a method of vision correction wherein corneal tissue is removed and the newly created surface is smoothed. No reference to any aspect of energy density is made in relation to the teachings of U.S. Patent No 4,988,348 as mentioned in U.S. Patent No 6,110,166. In fact, the term "optimized pulse energy density above a minimum level" is wholly absent from both the disclosure of U.S. Patent No 4,988,348 and U.S. Patent No 6,110,166. Thus applicant's assertion that the term "optimized pulse energy density above a minimum level" is in any way supported by either of these documents, or in any way part of the originally filed disclosure of the instant application is not convincing.

Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, as originally filed does not provide support for the invention as now claimed. Specifically there is no disclosure of an “optimized pulse energy density above a minimum level” either expressly, by incorporation, or by inference in the originally filed disclosure, nor is the particular density claimed so supported.

Similarly, applicant’s allegation that the claimed subject matter, which finds no support in either of the parent cases, predates the filing date of Ito et al, is not convincing, as no showing has been made of a date for the added material prior to June 9, 2004. It is noted, however, that even assuming applicant does find support for the amended material that predates Ito et al, the disclosure of U.S. Patent No 4,988,348 would still predate all of applicant’s filing dates.

With regard to the subject matter accorded the filing date of parent case 08/407,508, this is merely the ablation of corneal tissue. The disclosure of parent case 08/407,508 is devoid of any mention of a “optimized pulse energy density above a minimum level”; or “creating a peripheral edge” as defined in the instant claims. Nor is any flap disclosed in the parent, thus the lifting, etc. steps associated with this aspect of the claimed invention is also completely absent therefrom.

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With regard to the obviousness rejections, applicant's arguments appear based on the uncombinability of the references, presumably because Stern et al discuss a different energy density than that of Swinger et al. The examiner must note that given the complete absence of any disclosed "optimized pulse energy density above a minimum level" and in view of the fact that the claimed method simply discussed "photoalteration" of the stroma, the energy levels of either Stern et al or Swinger et al would read on the claims equally. It is further noted that the applied rejections (even assuming the "optimized pulse energy density above a minimum level" can be construed as referring only to photoablation) make the combination by either employing the densities of Stern et al in the method of Swinger et al or the cut patterns of Swinger et al in the method of Stern et al, the latter combination would not be taught away from, as Swinger does not state that higher energy densities would not work, merely that they are non-preferred. Thus these arguments are not convincing.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 12-17, 22, 24-36, 39, and 40 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ito et al.

Ito et al teach formation of a "lens shaped" lenticle to be removed from the cornea the 20 micron diameter spots at 40 and 60 microjoules are above the value asserted to be designated by the claimed "minimum pulse energy density", various (concave, convex, spiral, circular) shapes

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are disclosed in either aplanated or non-aplanated configuration (see text starting at the first full paragraph in column 1 of page 723 to the end of the first full paragraph at column 1 of page 727.

Claims 24-37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swinger et al in combination with Stern et al. Swinger teaches a method as claimed except the energy density discussed in the claims. Stern et al teach the desirability of employing pulse energies above the minimum ablation threshold. It would have been obvious to the artisan of ordinary skill to employ the energy densities of Stern et al in the method of Swinger et al, since this removes tissue in a plasma regime, which yields increasing depth as pulse energy increases (see Fig 1 of Stern) or to employ the ablation configuration of Swinger et al in the method of Stern et al, since this yields efficacious optical corrections, and in either case, to form the flap as an oval, since this would leave undisturbed a larger amount of tissue in the case of an astigmatic ablation, thus producing a method such as claimed).

Claims 12-20, 22, 23, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swinger et al in combination with Stern et al as applied to claims 24-37 and 40 above, and further in combination with Warner et al. Warner et al teach the equivalence of forming a cap and forming a flap. It would have been obvious to the artisan of ordinary skill to form a flap in the method of Swinger et al since these are equivalents, as shown by Warner et al and because the accurate replacement of a flap is more easily achieved than with a cap, official notice of which is hereby taken, thus producing a method such as claimed.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swinger et al in combination with Stern et al and Warner et al as applied to claims 12-20, 22, 23 and 39 above, and further in combination with Bronstein. Bronstein teaches forming an interlocking feature,

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which can take the form of a tab to affix an implant to the cornea. It would have been obvious to take artisan of ordinary skill to form a structure as taught by Bornstein on the flap of Warner et al since this would help affix the flap in placing during healing.

Applicant's arguments filed July 11, 2005 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

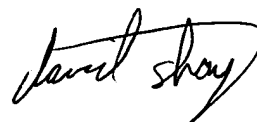
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on Monday, Tuesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David M. Shay", with a stylized flourish at the end.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330